JUN 2 9 2000

K001080

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

in Accordance with SMDA of 1990

SPINE SYSTEM® EVOLUTION

April 3, 2000

COMPANY: Aesculap®, Inc.
1000 Gateway Blvd.
So. San Francisco, CA 94080

CONTACT: Lia S. Jones, Regulatory Associate
650-624-5073 (phone)
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TRADE NAME: Spine System® Evolution

COMMON NAME: Posterior Spinal Fixation System

DEVICE CLASS: Class II

PRODUCT CODE(S): KWP, MNH, MNI

CLASSIFICATION(S): 888.3050 – Spinal Interlaminal Fixation Orthosis
888.3070 – Spondylolisthesis Spinal Fixation Device System
888.3070 – Pedicle Screw Spinal System

REVIEW PANEL: Orthopedic Devices Branch
Division of General and Restorative Devices

DEVICE DESCRIPTION

Spine System Evolution is a multiple component system comprised of a variety of single-use, non-sterile implants (Ti6Al4V acc. to ISO 5832/3) that allow the surgeon to build a spinal construct in order to stabilize and promote fusion in the thoracic, lumbar and sacral spine. It is a low-profile, top-loading system that utilizes one connection (conical nut) for all implants, such as standard and polyaxial pedicle screws, sacral plates and screws, rods and rod connectors, linking plates, lateral connectors, and various hook styles and configurations.

PURPOSE OF PREMARKET NOTIFICATION

This submission seeks to expand the current product line for Aesculap's Spine System Evolution (K980484, K982914) with new and modified components. There are no changes to the intended use, material composition or fundamental scientific technology.

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SPINE SYSTEM® EVOLUTION

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INDICATIONS FOR USE

Spine System Evolution is a pedicle screw system indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

In addition, Spine System Evolution is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

When used as a posterior, non-cervical, non-pedicle screw fixation system, Spine System Evolution is intended for hook fixation from T1 to the ilium / sacrum. The non-pedicle screw indications are degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (fracture or dislocation), spinal stenosis, deformities or curvatures (scoliosis, kyphosis and lordosis), tumor, pseudoarthrosis, and/or failed previous fusion.

PERFORMANCE DATA

No performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for this device system. The implants presented in this 510(k), however, were put through various test methods in accordance to applicable ISO / ASTM standards in order to establish their safety and efficacy.

SUBSTANTIAL EQUIVALENCE

The new and modified components described in this premarket notification are substantially equivalent in their intended use, material composition, labeling, design and basic operating principles to those in Aesculap's current Spine System Evolution (K980484, K982914), as well as the following competitor spinal systems:

- ISOBAR®, ISOLOCK® Spinal System (K992738, K990118, K990721)
- ISOLA / VSP System (K984350)
- Mirage™ Spinal System (K951846)
- Xia™ Spinal System (K992792, K984251)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 9 2000

Ms. Lia S. Jones
Regulatory Associate
Aesculap, Incorporated
1000 Gateway Boulevard
South San Francisco, California 94080-7028

Re: K001080
Trade Name: Spinal System® Evolution
Regulatory Class: II
Product Code: KWP, MNH and MNI
Dated: April 3, 2000
Received: April 4, 2000

Dear Ms. Jones:

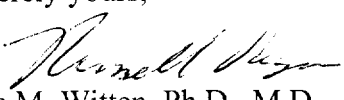
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K001080

Device Name: **Spine System® Evolution**

Indication for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Orthopedic and Restorative Devices
510(k) Number K001080

Prescription Use X or Over-the-Counter Use _____

(per 21 CFR 801.109)

(Optional Format 3-10-98)